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Customer No.: 07278
PATENT TRADEMARK OFFICE

Docket No:0342/1H395US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Vadim BICHKO

Serial No.: 10/005,469 Art Unit: 1648

Confirmation No.: 7244

Filed: November 7, 2001 Examiner: Li, Bao Q

For: HEPATITIS C VIRUS CONSTRUCTS CHARACTERIZED BY HIGH EFFICIENCY REPLICATION

RESPONSE TO RESTRICTION REQUIREMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

February 28, 2003

Sir:

In response to the Official Action dated January 28, 2003, please consider the following remarks.

Response Under 35 U.S.C. § 121

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. § 121:

Group I: Claims 1-3 and 5, drawn to an isolated nucleic acid molecule encoding a replication competent recombinant hepatitis C virus (HCV).

Group II: Claims 6-11, drawn to an isolated nucleic acid molecule encoding a fragment of HCV.

Group III: Claims 4 and 12-13 (sic, 12-19), drawn to a cell line transfected with a nucleic acid molecule.

Group IV: Claim 20, drawn to a method for screening an anti-HCV therapeutics.

Group V: Claims 21-22, drawn to a method for detecting antibodies against HCV.

In order to be fully responsive to the Requirement for Restriction, Applicant elects, with traverse, to prosecute claims 1-3 and 5, corresponding to the claims of Group I, and double stranded DNA as the species nucleic acid molecule.

Applicant respectfully traverses the Requirement for Restriction and reserves the right to petition therefrom under 37 C.F.R. § 1.144. In particular, Applicant respectfully requests modification of the Restriction Requirement to allow prosecution of more than one group.

Groups I and II should be examined together. Although claim 6 is of different scope, the subject matter of claim 6 is the same as the subject matter of claim 1. The subject matter of Group II is completely embraced by Group I.

Groups I and III should be examined together. The stable cell lines of Group III are transfected with the isolated nucleic acid of Group I, and consequently, fall within the same group. Indeed, these claims depend directly or indirectly on claim 1. Moreover, it is standard practice in Group 1600 to examine cells comprising a recombinant nucleic acid with the nucleic acid, along with methods of expressing the nucleic acid. See also 35 U.S.C. § 103(b).

A thorough search of the subject matter of the claims of Group I would necessarily include a search of the subject matter of the claims of Group II and Group III, as they all involve recombinant HCV nucleic acid sequences.

Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions." See, M.P.E.P. § 803 (emphasis added). The groups of claims designated by the Examiner (*i.e.*, Groups I, II and III, *supra*) do not define products which warrant separate examination and searches. Rather, the claims represent a web of knowledge and continuity of effort that merits examination in a single application. The conjoint examination and inclusion of all of the claims of groups I, II and III in the instant application is therefore appropriate and would not present an undue burden on the Examiner.

Applicant takes issue with the Examiner's contention that the species of nucleic acids (double stranded DNA, single stranded DNA, double stranded RNA, and single stranded RNA) are all distinct inventions (not species) of the genus nucleic acid

molecule. The Examiner does not provide any evidence or reason why these have different patentable weight, but even if that is true, that is often the case for individual species of an invention. The fact remains that the genus "nucleic acid molecule" embraces these species of nucleic acids, as is well known in the art, and these all fall in the same statutory class of invention. The Examiner has provided no evidence supporting any other conclusion.

In view of the request to rejoin claims 6-11 with claims 1-3 and 5, Applicant has elected SEQ ID NO: 4 as the species of sequence. All of these sequences are 95 to 99.9% identical to SEQ ID NO:1. Furthermore, the sequences are shown to be replication competent to HCV genomes. Accordingly, these sequences are species of the nucleic acid of claim 1. They are all species of the genus "nucleic acid molecule encoding a replication competent recombinant HCV genome". The Examiner does not provide any reason why these have different patentable weight, but even if that is true, that is often the case for different species of an invention. Indeed, as shown in the Examples, HCVR9 and HCVR24 grow at nearly the same rate as parental Huh-7 host cells, while other isolates (HCVR 2, 8, and 22) reduced growth rate by only 4-fold (see page 39). All of these isolates share a great deal of sequence similarity to SEQ ID NO: 1, but nevertheless are not identical, with at least from 3 to 5 sequence changes present. The fact that species are distinguishable from each other is a necessary feature of being a species of a genus. These nucleic acids also fall int the same statutory class, indeed the same type of molecule, as the genus of claim 1. They are, accordingly, related species of the same

genus.

Finally, Applicant takes issue with the contention that the species of cell line recited in claim 13 are distinct inventions. Again, all of these cell lines are species of the genus recited in claim 12, which are all modified by incorporating the nucleic acid of claim 1. Furthermore, HCRV 2, HCVR 8, HCVR 9, HCVR 22, and HCVR 24 are Huh-7 cells transfected with nucleic acids embraced by claim 1 as discussed above. The genus host cell embraces all of these species, and the Examiner does not provide any evidence or reason to dispute this.

In view of the foregoing, Applicant elects double stranded DNA as the species of nucleic acid. All of claims 1-19 read on this species.

Furthermore, Applicant elects SEQ ID NO: 4 as the species of construct. Claims 1-6, 9, 12-14, and 17 read on this species.

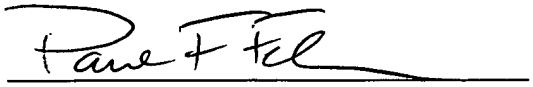
In addition, Applicant elects Huh-7 as the species of host cell. Claims 1-19 all read on this species.

Applicant would, upon modification of the Restriction Requirement to include claims 1-19, elect these claims without traverse. In addition, Applicant would elect the species of double stranded DNA as the species of nucleic acid, the sequence of SEQ ID NO: 4 as the species of nucleic acid, and the species of Huh-7 cells as the species of susceptible cell line.

CONCLUSION

In view of the above remarks, modification of the Requirement for Restriction is respectfully requested, and an early action on the merits is courteously solicited.

Respectfully submitted,



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